

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Daniel Altman  
 KNOBBE, MARTENS, OLSON & BEAR, LLP  
 2040 Main Street  
 Fourteenth Floor  
 Irvine, California 92614

**PCT**

**NOTIFICATION OF TRANSMITTAL OF  
 THE INTERNATIONAL SEARCH REPORT AND  
 THE WRITTEN OPINION OF THE INTERNATIONAL  
 SEARCHING AUTHORITY, OR THE DECLARATION**

(PCT Rule 44.1)

Applicant's or agent's file reference  ANVIL.001BPC	Date of mailing (day/month/year)  05 JUN 2006
International application No.  PCT/US05/36987	FOR FURTHER ACTION See paragraphs 1 and 4 below  International filing date (day/month/year) 13 October 2005
Applicant ANVIL MEDICAL, INC.  •	

1.  The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2.  The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3.  With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.  
 no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US  Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer:  Blaine R. Copenheaver  Telephone No. 571-272-7774
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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ANVIL.001BPC	<b>FOR FURTHER ACTION</b>	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US05/36987	International filing date (day/month/year) 13 October 2005	(Earliest) Priority Date (day/month/year) 13 October 2004
Applicant ANVIL MEDICAL, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the language, the international search was carried out on the basis of:

the international application in the language in which it was filed  
 a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b.  With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2.  Certain claims were found unsearchable (see Box No. II)

3.  Unity of invention is lacking (see Box No. III)

4. With regard to the title,

the text is approved as submitted by the applicant  
 the text has been established by this Authority to read as follows:

5. With regard to the abstract,

the text is approved as submitted by the applicant  
 the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

as suggested by the applicant  
 as selected by this Authority, because the applicant failed to suggest a figure  
 as selected by this Authority, because this figure better characterizes the invention

b.  none of the figures is to be published with the abstract

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/36987

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
  
  
  
  
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
  
  
  
  
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group I, claims 1-11, 14-28, drawn to a prosthesis and deployment catheter system having at least one frond.  
Group II, claims 12-13, drawn to a prosthesis and deployment system assembly, comprising: a catheter body; a balloon on the body, the balloon having an inflated profile  
Group III, claim 29, drawn to a dual guidewire catheter for treating vascular bifurcation.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of a prosthesis and deployment catheter system having at least one frond as in Group I is not present in Groups II or III; the special technical feature of a prosthesis and deployment system assembly, comprising: an elongate, flexible catheter body; a balloon on the body, the balloon having an inflated profile with a first section having a first diameter, a second section having a second diameter, and a balloon transition in the first and second sections; and a prosthesis carried by the balloon; wherein the prosthesis has a wall having a first wall pattern adjacent the first section of the balloon, and a second wall pattern adjacent the balloon transition of Group II is not present in Group I and/or Group III; the special technical feature of the specifics of a dual guidewire catheter for treating vascular bifurcation as in Group III is not present in Groups I or II.

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
  
  
  
  
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1-11 and 14-28

## Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US05/36987

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - A61F00206 (2006.01) USPC - 623/1.35, 1.15, 1.16 According to International Patent Classification (IPC) or to both national classification and IPC																																											
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61F 002/06 (2006.01) USPC - 623/1.35																																											
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched																																											
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Micropatent, USPAT, USPGPUB, Entrez PubMed																																											
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 2px;">Category*</th> <th style="text-align: left; padding: 2px;">Citation of document, with indication, where appropriate, of the relevant passages</th> <th style="text-align: left; padding: 2px;">Relevant to claim No.</th> </tr> </thead> <tbody> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 5,868,777 A (LAM) 09 February 1999 (09.02.1999) entire document, col 3 ln 42-54</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 6,663,665 B2 (SHAOILIAN et al) 16 December 2003 (16.12.2003) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 6,663,666 B1 (QUIACHON et al) 16 December 2003 (16.12.2003) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 6,682,557 B1 (QUIACHON et al) 27 January 2004 (27.01.2004) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 6,325,826 B1 (VARDI et al) 04 December 2001 (04.12.2001) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 6,210,429 B1 (VARDI et al) 03 April 2001 (03.04.2001) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 6,599,316 B2 (VARDI et al) 29 July 2003 (29.07.2003) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 6,596,020 B2 (VARDI et al) 22 July 2003 (22.07.2003) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 4,994,071 A (MACGREGOR) 19 February 1991 (19.02.1991) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 5,102,417 A (PALMAZ) 07 April 1992 (07.04.1992) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 5,342,387 A (SUMMERS) 30 August 1994 (30.08.1994) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 5,507,769 A (MARIN et al) 16 April 1996 (16.04.1996) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> <tr><td style="padding: 2px;">A</td><td style="padding: 2px;">US 5,575,817 A (MARTIN) 19 November 1996 (19.11.1996) entire document</td><td style="padding: 2px;">1-11, 14-28</td></tr> </tbody> </table>		Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	A	US 5,868,777 A (LAM) 09 February 1999 (09.02.1999) entire document, col 3 ln 42-54	1-11, 14-28	A	US 6,663,665 B2 (SHAOILIAN et al) 16 December 2003 (16.12.2003) entire document	1-11, 14-28	A	US 6,663,666 B1 (QUIACHON et al) 16 December 2003 (16.12.2003) entire document	1-11, 14-28	A	US 6,682,557 B1 (QUIACHON et al) 27 January 2004 (27.01.2004) entire document	1-11, 14-28	A	US 6,325,826 B1 (VARDI et al) 04 December 2001 (04.12.2001) entire document	1-11, 14-28	A	US 6,210,429 B1 (VARDI et al) 03 April 2001 (03.04.2001) entire document	1-11, 14-28	A	US 6,599,316 B2 (VARDI et al) 29 July 2003 (29.07.2003) entire document	1-11, 14-28	A	US 6,596,020 B2 (VARDI et al) 22 July 2003 (22.07.2003) entire document	1-11, 14-28	A	US 4,994,071 A (MACGREGOR) 19 February 1991 (19.02.1991) entire document	1-11, 14-28	A	US 5,102,417 A (PALMAZ) 07 April 1992 (07.04.1992) entire document	1-11, 14-28	A	US 5,342,387 A (SUMMERS) 30 August 1994 (30.08.1994) entire document	1-11, 14-28	A	US 5,507,769 A (MARIN et al) 16 April 1996 (16.04.1996) entire document	1-11, 14-28	A	US 5,575,817 A (MARTIN) 19 November 1996 (19.11.1996) entire document	1-11, 14-28
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<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																																											
Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed																																											
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family																																											
Date of the actual completion of the international search	Date of mailing of the international search report																																										
10 March 2006	05 JUN 2006																																										
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/J.S. Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee. W. Young Telephone No. 571-272-7774																																										

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To: Daniel Altman  
KNOBBE, MARTENS, OLSON & BEAR, LLP  
2040 Main Street  
Fourteenth Floor  
Irvine, California 92614

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

<p>Date of mailing (day/month/year)</p>		<b>05 JUN 2006</b>
<p>Applicant's or agent's file reference ANVIL.001BPC</p>		<p><b>FOR FURTHER ACTION</b> See paragraph 2 below</p>
<p>International application No. PCT/US05/36987</p>	<p>International filing date (day/month/year) 13 October 2005</p>	<p>Priority date (day/month/year) 13 October 2004</p>
<p>International Patent Classification (IPC) or both national classification and IPC IPC(8) - A61F00206 (2006.01) USPC - 623/1.35, 1.15, 1.16</p>		
<p>Applicant ANVIL MEDICAL, INC.</p>		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Date of completion of this opinion 10 March 2006	Authorized officer: Lee W. Young Telephone No. 571-272-7774
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US05/36987

Box No. I Basis of this opinion
<p>1. With regard to the language, this opinion has been established on the basis of:</p> <p><input checked="" type="checkbox"/> the international application in the language in which it was filed</p> <p><input type="checkbox"/> a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).</p> <p>2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:</p> <p>a. type of material</p> <p><input type="checkbox"/> a sequence listing</p> <p><input type="checkbox"/> table(s) related to the sequence listing</p> <p>b. format of material</p> <p><input type="checkbox"/> on paper</p> <p><input type="checkbox"/> in electronic form</p> <p>c. time of filing/furnishing</p> <p><input type="checkbox"/> contained in the international application as filed</p> <p><input type="checkbox"/> filed together with the international application in electronic form</p> <p><input type="checkbox"/> furnished subsequently to this Authority for the purposes of search</p> <p>3. <input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.</p> <p>4. Additional comments:</p>

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US05/36987

Box No. IV Lack of unity of invention

1.  In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
  - paid additional fees
  - paid additional fees under protest and, where applicable, the protest fee
  - paid additional fees under protest but the applicable protest fee was not paid
  - not paid additional fees
2.  This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is:
  - complied with
  - not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-11, 14-28, drawn to a prosthesis and deployment catheter system having at least one frond.

Group II, claims 12-13, drawn to a prosthesis and deployment system assembly, comprising: an elongate, flexible catheter body; a balloon on the body, the balloon having an inflated profile with a first section having a first diameter, a second section having a second diameter, and a balloon transition in between the first and second sections; and a prosthesis carried by the balloon; wherein the prosthesis has a wall having a first wall pattern adjacent the first section of the balloon, and a second wall pattern adjacent the balloon transition.

Group III, claim 29, drawn to a dual guidewire catheter for treating vascular bifurcation.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of a prosthesis and deployment catheter system having at least one frond as in Group I is not present in Groups II and/or III; the special technical feature of a prosthesis and deployment system assembly, comprising: an elongate, flexible catheter body; a balloon on the body, the balloon having an inflated profile with a first section having a first diameter, a second section having a second diameter, and a balloon transition in between the first and second sections; and a prosthesis carried by the balloon; wherein the prosthesis has a wall having a first wall pattern adjacent the first section of the balloon, and a second wall pattern adjacent the balloon transition of Group II is not present in Group I and/or Group III; the special technical feature of the specifics of a dual guidewire catheter for treating vascular bifurcation as in Group III is not present in Groups I and/or II.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- all parts
- the parts relating to claims Nos. 1-11, 14-28

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US05/36987

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	1-11, 14-28	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-11, 14-28	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-11, 14-28	YES
	Claims	None	NO

**2. Citations and explanations:**

Claims 1-11 and 14-28 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the limitations of claims 1 and 14 including a prosthesis for placement at an opening from a main body lumen to a branch body lumen, the prosthesis having both one or a plurality of fronds extending axially from an end of the support and configured to be positioned across the Os and into the main body lumen and at least one circumferential link connected to the frond(s), the circumferential link spaced axially apart from the support, wherein the circumferential link is carried by a second portion of a balloon which is inflatable to a second diameter that is larger than the first diameter. Close prior art is US 5868777 to Lam. Lam discloses that after the ostial stent is positioned within the diseased bifurcated vessel, balloon catheters are employed to secure the ostial stent in position. By expanding the balloon carrying the ostial stent, the tubular body is seated within the diseased portion of the bifurcated vessel extending away from the bifurcation and the flaring portion is configured to "cap" the ostium to the diseased portion of the vessel. In the alternative, a series of various sized and shaped balloon catheters can be employed to configure the ostial stent so that it seats within and "caps" the ostium to the diseased portion of the bifurcation or a bi- or tri-balloon system may be employed to properly implant the tubular body and flaring portion of the ostial stent (col 3 ln 42-54). Furthermore, Lam discloses a flaring portion 25 is capable of expanding and may be comprised of individual petals 26 or in the alternative and as shown in FIGS. 4 and 5, the flaring portion 25 may comprise malleable material 28 (col 5 ln 65 - col 6 ln 1). It is clear from Lam's figures 4 and 5 that the flaring portion 25 (which might be construed as a circumferential link) is connected to and not spaced axially apart from the support.)

Claims 1-11 and 14-28 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

## NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

### "Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

#### What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

**When ?** Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

**How ?** Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

**The amendments must be made in the language in which the international application is to be published.**

#### What documents must/may accompany the amendments ?

##### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.